

4. 510(k) Summary

Submitted by: The Procter & Gamble Company
6110 Center Hill Avenue
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Contact Person: Mark M. Anderson, Regulatory Affairs Manager
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Date Summary Prepared: May 10, 2005

Trade Name: TAMPAX® Pearl Plastic Applicator Tampons
(unscented and scented)

Common Name: Unscented Menstrual Tampon;
Scented Menstrual Tampon

Classification Name: Unscented Menstrual Tampon (21 CFR 884.5470);
Scented or Scented Deodorized Menstrual Tampon
(21 CFR 884.5460)

Predicate Devices: TAMPAX® Pearl Plastic Applicator Tampons,
Procter & Gamble, K011996

TAMPAX® Pearl Plastic Applicator Tampons,
Procter & Gamble, K040312

Device Description: The device is a conventional menstrual tampon consisting of an absorbent pledget, a withdrawal cord, and a plastic applicator. It is available in both scented and unscented versions.

- The absorbent pledget consists of a chevron-shaped pad of cotton and/or rayon fibers. The pad is overwrapped with a non-woven fabric. A cotton withdrawal cord with absorbent rayon fibers adjacent to the pad is sewn to the pad. For scented tampons, fragrance is applied to the pad. For both scented and unscented tampons, the pad is compressed into a traditional bullet-shaped pledget.
- The formed pledget is inserted into a plastic applicator consisting of an outer insertion tube and an inner pusher tube. Flexible petals form a closed, rounded tip at the distal end of the outer applicator tube.
- Each tampon is wrapped in an individual plastic film wrapper and packaged in sealed multi-unit containers for retail sale.

Intended Uses: The device is intended to be inserted into the vagina to absorb menstrual fluid.

Technological Characteristics: The device is similar to the predicate devices in terms of component materials and overall design (see *Device Description*, above). The device differs from the predicate devices in the amounts of component materials used and the dimensions of the finished tampons as well as in the colorants used in certain components.

Safety Assessment: The 510(k) device was subjected to a battery of safety tests, including *in vitro* and clinical testing. The results of these safety tests support the conclusion that the 510(k) device is equally as safe as the predicate devices.

Effectiveness: The 510(k) device tampons comply with the Syngyna absorbency requirements of 21 CFR 801.430. Therefore, additional testing of these tampons is not necessary to establish their equivalence to the predicate tampons in terms of effectiveness.

Conclusions: The results of evaluations of this device support the conclusions that it is safe for its intended use and that it is substantially equivalent to the cited predicate devices with regard to safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2005

Mark M. Anderson, Ph.D.
Regulatory Affairs Manager
The Proctor & Gamble Company
The Winton Hill Business Center
Product Safety & Regulatory Affairs
6110 Center Hill Avenue
CINCINNATI OH 45224

Re: K051290
Trade/Device Name: TAMPAX® Pearl Plastic Applicator Tampons, Ultra Absorbency
(unscented and scented)
Regulation Number: 21 CFR §884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: September 28, 2005
Received: September 30, 2005

Dear Dr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 1

3. Statement of Indications for Use

510(k) Number (if known): K051290

Device Name: TAMPAX® Pearl Plastic Applicator Tampons, Ultra Absorbency (unscented and scented)

Indications for Use:

TAMPAX® Pearl Plastic Applicator Tampons, Ultra Absorbency (unscented and scented) are menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid on day(s) of heaviest menstrual flow. Ultra absorbency should not be used on days of light or moderate flow.

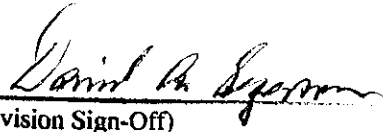
Prescription Use _____
(21 CFR Part 801 Subpart D)

AND/OR

Over-The-Counter Use ☒
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Allergy,
and Radiological Devices

510(k) Number K051290